

347



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,201	12/19/2001	Mary K. Crow	5983/1H567US1	5071
7590 05/10/2004				
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022		EXAMINER SAKELARIS, SALLY A		
		ART UNIT 1634		
		PAPER NUMBER		

DATE MAILED: 05/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/025,201

Applicant(s)

CROW, MARY K.

Examiner

Sally A Sakelaris

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See continuation sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.


Claim(s) rejected: 2,3 and 19-25.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_.

Continuation of 2. NOTE: The proposed amendment extensively modifies the claims and as a result will not be entered. The recitation of "comprises a sequence" in claim 3 and the new claims' use of similar open language raises issues under 112 1st paragraph written description and include new limitations such as "wherein the region of the genome is within 5 million/1.7 cM on either side of the SLE-associated marker" that require a new search of the prior art.

Continuation of 5. does NOT place the application in condition for allowance because: The applicant's traversal on the grounds that the last office action could not have been made final "based upon claim limitations already examined prior to the issuance of the first office action" is not found to be convincing as such limitations that were newly rejected in the final action were not present in the claims examined in the first action on the merits of the case. Specifically, the limitation of "comprises a sequence" was a newly amended recitation and therefore the written description rejection was necessitated by applicant's amendments to the claims. Accordingly, the finality of the January 26, 2004 office action will not be withdrawn. Applicant further traverses the enablement rejection of the final office action on the grounds that "the Examples, particularly Examples 2 and 4, describe SLE susceptibility loci being found to be in proximity to L1 elements" and through citing references describing several of applicant's marker regions. While these articles and citations are noted, unless they are present in declaration format, their substance is not found to be convincing in arguing the presently maintained enablement rejection. The examiner is still trying to ascertain what properties of an L1 allow it to be functional at varying similarities to the consensus as well as at varying distances from the marker genes. Furthermore, in response to applicant's citation of articles, teaching that specific, SLE disease-associated markers are disclosed. While the examiner acknowledges that there are lists of "candidate genes", "proposed disease loci", and chromosomal locations, the examiner is not aware of a working example that featured the method as applied to an affected, or predisposed patient to SLE and the concurrent discovery of the associated marker and L1. While the cited art may in fact teach of the existence of markers well known in the art for SLE, the cited art is silent with respect to each of these known markers being associated with a L1 element of a certain % similarity located at a certain distance from the known marker. Next, while applicant's analysis of the wands factors is acknowledged, the examiner maintains that her previous analysis performed in the first two actions is maintained. Lastly, applicant traverses the rejection under written description by asserting that "there is no need for the skilled artisan to 'envision' each and every variant having a sequence identity within the claimed range, nor any need to compare its biochemical activity, because the present specification shows by experimental determination that L1 element having the structural feature of a high sequence similarity to SEQ ID NO:1 can identify candidate SLE genes located adjacent to an SLE-associated marker". While this assertion is acknowledged, it is not found to be convincing as the open claim language presently used to describe applicant's structural feature that is implicit in their presently claimed invention is not seen as meeting the requirements of written description. Furthermore, the remaining rejections are also maintained for reasons of record in view of the non-entry of after final amendment.

  
GARY BEN ZION, PH.D.  
SUPERVISORY PATENT EXAMINER  
TECHNICAL CENTER 1600  
5/17/04